A Response to the Office Action:

A. Status of the Claims

Claims 25-61 and 74-83 were pending at the time of the Office Action dated November 10, 2004. Claims 26-38, 47-61, and 76-81 have been withdrawn without prejudice or disclaimer as being directed to non-elected inventions. Thus, claims 25, 39-46, 74, 75, 82, and 83 were examined in the Office Action. Claims 25, 26, 32-35, 39-42, 44, 45, 50, 74, 75, 78, 81-83 have been amended. The claims now recite "*Chlamydia psittaci.*" In addition, the recitation "or antigenic fragment thereof" was deleted from claims 25, 26, 32, 39, 50, and 51, as this recitation was superfluous in these claims. No new subject matter was added by these amendments. Claims 28 and 47-49 have been canceled. New claims 84-91 have been added. Thus, claims 25-27, 29-46, 50-61, and 74-91 are pending.

B. The Rejections Under 35 U.S.C. § 102 Are Overcome

The Action rejects claims 25, 39-43, 45-46, 74-75, and 82-83 under § 102(e) as being anticipated by Griffais *et al.* (U.S. Patent No. 6,559,294). The Action also rejects claims 25, 39-43, 45-46, 74-75, and 82-83 under § 102(b) as being anticipated by Griffais *et al.* (WO 99/27105). Applicants traverse this rejection.

Applicants note that the disclosures of U.S. Patent No. 6,559,294 (the '294 patent) and WO 99/27105 appear to be the same. For convenience, Applicants will refer to these publications collectively as "Griffais *et al.*," and citations will be made to the '294 patent only.

To anticipate a claim, the prior art must teach every element of the claimed invention. The Action fails to identify where Griffais *et al.* teaches a method of immunizing an animal using a *Chlamydia psittaci* antigen, as required by the present claims. The Action states that Griffais *et al.* teach that antigen from *Chlamydia psittaci* may be included in the invention; however, the Action fails to show where Griffais *et al.* disclose a *Chlamydia psittaci* antigen

capable of eliciting an immune response in an animal. Thus, the Action fails to establish a *prima facie* case of anticipation.

Furthermore, the prior art must be enabling and describe Applicants' claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the art. *In re Paulsen*, 30 F.3d 1475 (Fed. Cir. 1994). The Action fails to show that Griffais *et al.* enable any method of immunizing an animal, much less the presently claimed method. Although Griffais *et al.* disclose a number of purported *Chlamydia pneumoniae* ORFs, there is no evidence as to which, if any, of these sequence are antigenic. Table 1 identifies some *Chlamydia psittaci* genes with homology to the *Chlamydia pneumoniae* ORFs, but provides no evidence as to which, if any, of these sequence are antigenic. Moreover, the '294 patent states that "[n]o vaccine is yet available against *Chlamydia pneumoniae:* this is due to the labile nature of the antigens specific to the strain, which has so far prevented their specific identification." (col. 4, ln. 26-29). The Action fails to show how Griffais *et al.* has overcome this art-recognized problem. Thus, a person of ordinary skill in the art would not have been placed in possession of a method of immunizing an animal by providing to the animal at least one *Chlamydia psittaci* antigen or antigenic fragment thereof in an amount effective to induce an immune response, because Griffais *et al.* does not teach which, if any, of the disclosed ORFs might be capable of eliciting an immune response.

In addition, present claims 40, 42, and 74 comprise a lower limit on the length of the sequences recited in these claims. These sequences are novel over prior art SEQ ID NO: 59 and SEQ ID NO:12 cited in the Action. New claims 85, 86, 90, and 91 also recite sequences that are novel over prior art SEQ ID NO: 59 and SEQ ID NO:12.

In view of the above, the Action fails to establish a *prima facie* case of anticipation because it has not shown that Griffais *et al.* teach all of the elements of the claims and describe

Applicants' claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the art.

C. The Rejections Under 35 U.S.C. § 112, First Paragraph, Are Overcome

The Action rejects claims 25, 39-46, 74-75, and 82-83 under § 112, first paragraph, for lack of enablement. Applicants traverse this rejection.

The Action acknowledges that the specification is enabling for a method of immunizing an animal comprising providing to the animal at least one *Chlamydia* antigen corresponding to SEQ ID NO: 9 or SEQ ID NO: 7 and further comprising a second *Chlamydia* antigen corresponding to SEQ ID NO: 11 or SEQ ID NO: 13. The Action, however, alleges that the specification is not enabling for all antigenic fragments of SEQ ID NOs: 7, 9, 11, and 13 encompassed by the claims. Applicants traverse this rejection.

As defined in the specification, an "antigenic fragment" refers to a fragment that can elicit an immune response in an animal (p. 13, ln. 19-20). The present specification demonstrates that the 443 amino acid polypeptide of SEQ ID NO:9 and the 100 amino acid polypeptide of SEQ ID NO:13 can be used to immunize an animal. The specification also demonstrates that a 149 amino acid fragment (SEQ ID NO:7) of SEQ ID NO:9 and a 41 amino acid fragment (SEQ ID NO:11) of SEQ ID NO:13 can be used to immunize an animal. A person of ordinary skill would be able to make and use these antigens and antigenic fragments, as well as other antigenic fragments of SEQ ID NOs: 9, 13, 7 and 11, by following the teachings of the present specification.

Guidance for a person of ordinary skill in the art to make antigenic fragments of SEQ ID NOs: 7, 9, 13, and 11 can be found in the specification as follows. First, the specification provides the nucleic acid and amino acid sequences of these antigens as a starting point from

which a person of ordinary skill in the art could make other antigenic fragments. Those of ordinary skill in the art understand that modifications and changes may be made in the structure of a gene and still obtain a functional molecule that encodes a protein or polypeptide with desirable characteristics. For example, it is known that certain amino acids may be substituted for other amino acids in a protein structure without appreciable loss of interactive binding capacity with antigen-binding regions of antibodies (Specification, p. 26, ln. 18-20). The specification teaches how the hydropathic index and/or hydrophilicty values can be used to alter protein structure while maintaining the biological property of the protein (p. 26, ln. 27 to p. 27, ln. 30).

Conservative substitutions taught by the specification, and well known in the art, include: alanine to serine; arginine to lysine; asparagine to glutamine or histidine; aspartate to glutamate; cysteine to serine; glutamine to asparagine; glutamate to aspartate; glycine to proline; histidine to asparagine or glutamine; isoleucine to leucine or valine; leucine to valine or isoleucine; lysine to arginine; methionine to leucine or isoleucine; phenylalanine to tyrosine, leucine or methionine; serine to threonine; threonine to serine; tryptophan to tyrosine; tyrosine to tryptophan or phenylalanine; and valine to isoleucine or leucine (p. 24, ln. 20-29).

Also as taught by the specification, antigenic determinants of a polypeptide may be identified by expressing portions of the gene encoding the polypeptide in a recombinant host, and assaying the resulting proteins for their ability to elicit an immune response (p. 25, ln. 8-20). For example, the polymerase chain reaction (PCR) can be used to prepare a range of cDNAs encoding peptides lacking successively longer fragments of the C-terminus of the protein. The immunogenic activity of each of these peptides then identifies those fragments or domains of the polypeptide that are essential for this activity. Further experiments in which only a small number of amino acids are

removed or added at each iteration then allows the location of other antigenic determinants of the polypeptide.

Applicants provide the Declaration of Akira Takashima, M.D., Ph.D. ("Takashima Declaration") as additional evidence that the specification enables antigenic fragments of SEQ ID NOs: 7, 9, 11, and 13 encompassed by the claims. The Takashima Declaration states that based on the teachings in the present specification, "a person of standard skill in molecular biology or immunology would understand an antigenic fragment of SEQ ID NOs: 7, 9, 11, or 13 to refer to a fragment of at least 5 contiguous amino acids of SEQ ID NOs: 7, 9, 11, or 13, but fewer than the full length of SEQ ID NOs: 7, 9, 11, or 13, capable of eliciting an immune response in an animal." (Takashima Declaration, ¶ 6).

The Takashima Declaration also states that the data presented in the present specification demonstrate that the 443 amino acid polypeptide of SEQ ID NO: 9 can be used to immunize an animal; and that a 149 amino acid fragment (SEQ ID NO: 7) of SEQ ID NO: 9 can also be used to immunize an animal. (Takashima Declaration, ¶ 7). The Takashima Declaration also states that the data presented in the present specification demonstrate that the 100 amino acid polypeptide of SEQ ID NO: 13 can be used to immunize an animal; and that a 41 amino acid fragment (SEQ ID NO: 11) of SEQ ID NO: 13 can also be used to immunize an animal. (Takashima Declaration, ¶ 8). The Takashima Declaration states that, based on these results, a scientist will understand that there would likely be other antigenic fragments of SEQ ID NOs: 7, 9, 11, and 13 that would elicit an immune response in an animal. (Takashima Declaration, ¶¶ 7 and 8).

A scientist will understand that there would likely be other antigenic fragments of SEQ ID NOs: 7, 9, 11, and 13 that would elicit an immune response in an animal, because it is known

to scientists in the fields of molecular biology and immunology that immunogenic proteins typically contain multiple immunogenic epitopes or determinants. (Takashima Declaration, ¶ 10). Furthermore, the Takashima Declaration states that a scientist of standard skill would be capable of identifying antigenic fragments of SEQ ID NOs: 7, 9, 11, and 13 by following the teachings in the specification. (Takashima Declaration, ¶ 10).

The Takashima Declaration notes, for example, that antigenic determinants of a polypeptide may be identified by preparing and assaying a range of cDNAs encoding peptides lacking successively longer fragments of the C-terminus of the polypeptide as described in the present specification at page 25, lines 8-20. (Takashima Declaration, ¶ 10). Scanning a full-length antigenic polypeptide for antigenic epitopes or determinants is routine in the field of immunology. (Takashima Declaration, ¶ 10). Thus, a scientist of standard skill in molecular biology or immunology could identify antigenic fragments of SEQ ID NOs: 7, 9, 11, and 13 using only routine screening techniques as described in the present specification. (Takashima Declaration, ¶ 10). In conclusion, the Takashima Declaration states that "a molecular biologist or immunologist could practice the presently claimed invention using antigenic fragments of SEQ ID NOs: 7, 9, 11, or 13 by following the teachings of the present specification." (Takashima Declaration, ¶ 11).

For the reasons above, a person of ordinary skill would be able to make and use antigenic fragments of SEQ ID NOs: 7, 9, 11, and 13 by following the teachings of the present specification. Likewise, a person of ordinary skill would be able to make and use antigenic fragments of other *Chlamydia* antigens disclosed in the specification.

Applicants also point out that claims 40, 42, and 74 have been amended to place a lower limit on the length of the antigenic fragment. In addition, new claims 84-91 place a lower limit

on the length of the antigenic fragment. For example, claim 85 recites, in part, "wherein the antigenic fragment comprises at least 25 contiguous amino acid residues of SEQ ID NO:9...." This reduces the number of fragments encompassed by these claims as compared to claims in which no lower limit is placed on the length of the fragment.

In view of the above, Applicants request the withdrawal of this rejection.

D. The Rejections Under 35 U.S.C. § 112, First Paragraph, Are Overcome

The Action rejects claims 25, 39-46, 74-75, and 82-83 under § 112, second paragraph, as being indefinite. Specifically, the Action asserts that the recitation of "providing to the animal" in claim 25 is unclear. Applicants traverse this rejection.

The claims must define the patentable subject matter with a reasonable degree of clarity. "Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire." MPEP § 2173.02. Applicants submit that the recitation "providing to the animal" in the context of a method of immunizing an animal is reasonably clear to those of ordinary skill in the art. Applicants, therefore, request the withdrawal of this rejection.

E. The Objection to Claims 40 and 41

The Action objects to claims 40 and 41 because they depend from a succeeding claim. Applicants acknowledge that claims 40 and 41 currently depend from claim 82. Applicants note, however, that in situations where a claim refers to a numerically following claim and the dependency is clear, no objection to form should be made. In such cases, the Examiner will renumber the claims into proper order at the time the application is allowed. *See* M.P.E.P. §§ 608.01(n)(I)(F) and 608.01(n)(IV). Applicants, therefore, request that this objection be withdrawn.

D. Conclusion

Applicants believe this to be a full and complete response to the Office Action dated November 10, 2004. Applicants, therefore, respectfully request that the rejections to all claims be withdrawn so they may pass to issuance.

The Examiner is invited to contact the undersigned attorney at (512) 536-3035 with any questions, comments or suggestions relating to the referenced patent application.